UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ELECTRICAL WORKERS INSURANCE FUND,

Plaintiff,

v.

KATHLEEN SEBELIUS, in her official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant.
_____/

Case No. 08-14738

Honorable Nancy G. Edmunds

OPINION AND ORDER GRANTING DEFENDANT'S MOTION TO DISMISS [51]

This matter comes before the Court on Defendant's motion to dismiss [51]. Plaintiff Electrical Workers Insurance Fund ("Fund") is a jointly administered trust fund that provides health benefits to active and retired members of the Electrical Workers Local Union No. 58. It brought this lawsuit against the Secretary of Health and Human Services ("HHS" or the "Secretary")[1] challenging the Secretary's refusal to allow the Fund to submit a December 6, 2007 reimbursement claim in the amount of approximately $400,000 for prescription drug benefits paid on behalf of its participants under Medicare Part B through the Indirect Payment Procedure authorized by and implemented in 42 U.S.C. § 1395u(b)(6)(B); 42 C.F.R. 424.66. (Pl.'s Am. Compl., ¶¶ 23-32). Plaintiff's lawsuit sought declaratory,

[1]HHS is the governmental agency charged with the administration of the Medicare Act, 42 U.S.C. § 1395, *et seq.*, including the promulgation of regulations for the administration of the Medicare payment policies and procedures.

injunctive, and mandamus relief; specifically: (1) "a judgment declaring that the Fund is entitled to reimbursement, pursuant to 42 U.S.C. § 1395u(b)(6)(B) and 42 C.F.R. 424.66 ("the Indirect Payment Procedure"), for benefit payments made by the Fund that were payable under the Medicare Act;" (2) "a writ of mandamus ordering and directing the HHS and its authorized representatives to accept the Fund's claims for reimbursement for Part B drug claims . . . for processing and payment under the Indirect Payment Procedure;" and (3) "an order enjoining Defendant [HHS] from refusing to consider such claims under the Indirect Payment Procedure." (Pl.'s Am. Compl., ¶ 15.)

After the Fund filed this action, Defendant HHS reconsidered its earlier position and determined that the Indirect Payment Procedure ("IPP") process *would* be appropriate under the criteria set forth in 42 U.S.C. § 1395u(b)(6)(B) and 42 C.F.R. § 424.66. It acknowledged to this Court that it did not currently have an IPP in place to permit group health plans, like the Plaintiff Fund, to use that process. Thus, in response to the Fund's motion for summary judgment, HHS requested a voluntary remand so it could implement an IPP process like the one Plaintiff Fund was seeking and also develop policy and guidance regarding that IPP process. (Doc. No. 24, 2/15/10 Opin. at 5.)

On February 15, 2010, this Court granted Defendant HHS's motion for a voluntary remand, denied Plaintiff Fund's motion for summary judgment, stayed this action pending the publication and implementation of an IPP, and ordered that Defendant HHS comply with 42 U.S.C. § 1395u(b)(6)(B) and 42 C.F.R. § 424.66 in implementing the IPP and developing policy and guidance regarding the process. (*Id*. at 1, 12.) The Court clarified that "[t]he purpose of the remand" was to allow "HHS to devise a process by which [the Fund] can submit its Medicare Part B claims for reimbursement consistent with 42 U.S.C.

§ 1395u(b)(6)(B) and 42 C.F.R. § 424.66." (*Id.* at 8 n.9.) It further clarified that it would be "improper for this Court to dictate the specific manner for HHS to devise such an IPP." (*Id.*)

On April 20, 2012, in response to a motion filed by Plaintiff Fund, this Court lifted the stay in this matter for the limited purpose of allowing Defendant HHS to file a motion to dismiss. (Doc. No. 49, 4/20/12 Order.) Defendant HHS's motion is now before the Court. Because Plaintiff Fund received all the relief it is entitled to in its lawsuit and there is nothing further to litigate, this case is dismissed as moot. Defendant's motion to dismiss is GRANTED.

I. Facts

The Court is familiar with the background and procedural facts stated in its February 25, 2010 Opinion and Order [24] and above. The following statutory and regulatory background and additional facts are also relevant to HHS's motion to dismiss.

A. The Medicare Program

The Medicare program provides health insurance benefits to eligible aged and disabled persons. *See* Title XVIII of the Social Security Act, 42 U.S.C. § 1395*, et seq*. The program consists of four main parts: Parts A, B, C, and D. This case arises under Part B, which is a voluntary health insurance program subsidized by enrollee premiums and appropriated monies. *Id*. at §§ 1395j, 1395o, 1395r, 1395t. Part B provides payment for the services of physicians and other health practitioners, as well as a variety of "medical and other health services," which include a very limited category of outpatient drugs. *Id.* at §§ 1395k(a)(1), 1395x(s); 42 C.F.R. § 414.701. *See also* 42 C.F.R. Part 410 (scope of Part B benefits).

HHS, through the Centers for Medicare & Medicaid Services ("CMS"), contracts with

local private insurance "carriers" to administer the Part B claims process. 42 U.S.C. § 1395u; 42 C.F.R. § 421.200. A claim for Medicare Part B reimbursement must be timely submitted to the Medicare contractor. 42 C.F.R. §§ 424.32(a)(4), 424.44. Each Part B claim for items or services furnished by a physician or supplier must be supported by sufficient information and documentation for the Medicare contractor to determine whether the items or services are covered and the amount of any payment deemed owing. 42 U.S.C. § 1395l(e);[2] 42 C.F.R. § 424.5(a)(6).[3]

Wisconsin Physicians Service Insurance Corporation ("WPS") has entered into such a contract with CMS to serve as a contractor for Medicare Part B retiree health coverage in Michigan and certain other states. (Am. Compl., ¶ 8.)

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[2]Section 1395l(e) provides that:

> (e) Information for determination of amounts due
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> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e).

[3]42 C.F.R. § 424.5(a)(3) provides that:

> (a) As a basis for Medicare payment, the following conditions must be met:
>
> * * *
>
> (3) Beneficiary of services. Except as provided in § 409.68 of this chapter, the services must have been furnished while the individual was eligible to have payment made for them. (Section 409.68 provides for payment of inpatient hospital services furnished before the hospital is notified that the beneficiary has exhausted the Medicare benefits available for the current benefit period.)

B. Indirect Payment Process ("IPP")

CMS created an Indirect Payment Process ("IPP") in 1969, and amended that process in 1986, to allow a broader class of Complementary Insurers to submit Medicare Part B claims for reimbursement. As explained in the Federal Register, the 1986 amendments allow "any entity that meets the stated requirements of the indirect payment procedure" to use that procedure, including "employers, unions, insurance companies, and retirement homes." 51 Fed. Reg. 23792, 23793, 1986 WL 99370 (July 1, 1986). The IPP was described as:

> an effective and efficient method of settling Medicare and complementary insurance liabilities in cases in which (1) the complementary insurer knows before the submission of the Medicare claim that it is responsible for the full difference between the Medicare payment and the insurer's approved charge for the service and (2) the physician or supplier is prepared to accept the insurer's approved charge as full payment. It permits the physician or supplier to submit one bill (i.e., to the complementary insurer) and receive full payment in a single check; it relieves the beneficiary of the need to file a claim with Medicare, since the insurer files the Medicare claim; and it protects the beneficiary against any financial liability for the service.

Id. The IPP was further described as "an alternative to Medicare payment to the beneficiary on the basis of an itemized bill or to the physician or supplier on the basis of an assignment." *Id*. (emphasis added).

Under Medicare Part B, the payment for the services of a physician or supplier is generally 80% of reasonable charges in excess of an annual deductible amount. 53 Fed. Reg. 28384 (July 28, 1988). Upon submission of a properly executed claim, this payment is made to the beneficiary, or alternatively to the physician or supplier if he accepts assignment of the claim. 42 U.S.C. § 1395u(b)(6).

Some beneficiaries, however, have complementary insurance coverage that picks up

the beneficiaries' out-of-pocket expenses and pays (1) the annual deductible, (2) the 20% coinsurance, and (3) any amount by which the approved charge of the insurer exceeds the Medicare reasonable charge. 53 Fed. Reg. at 28384. Plaintiff Fund is a complementary insurer.

To provide an efficient method of settling Medicare and complementary insurance liabilities, Congress allows complementary insurers to receive Medicare Part B reimbursement directly as long as the complementary insurer: "(i) [ ] provide[d] coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) [ ] paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) [ ] the individual has agreed in writing that payment may be made under this part" to the complementary insurer. 42 U.S.C. § 1395u(b)(6)(B).[4]

The Medicare regulations further elaborate on the requirements a complementary insurer must meet in order to be eligible for Medicare B reimbursement. Specifically, the central regulation provides, in pertinent part, that:

(a) Conditions for payment. Medicare may pay an entity for Part B services

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[4]42 U.S.C. § 1395u(b)(6)(B) provides, in pertinent part, that:

> No payment under this part for a service provided to any individual shall (except as provided in section 1395gg of this title) be made to anyone other than such individual or ... the physician or other person who provided the service, except that ... (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part...

> furnished by a physician or other supplier if the entity meets all of the following requirements:
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> (1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).
>
> (2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.
>
> (3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 424.36) to receive the Part B payment for the services for which the entity pays.
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> (4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the beneficiary, his or her survivors or estate.
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> (5) Submits any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.
>
> (6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

42 C.F.R. § 424.66(a) (emphasis added).

C. Plaintiff Obtains Relief It Seeks - Access to IPP Process

After this Court granted Defendant's voluntary motion for a remand, HHS implemented an IPP process for entities like Plaintiff Fund and also developed policy and guidance regarding that IPP process, just as Plaintiff Fund sought in its amended complaint. As a result, the IPP process became newly operational on January 1, 2012, and accepts Medicare Part B claims with dates of service January 1, 2012 forward. (Def.'s Mot., Ex. 1, 10/07/11 ltr.) Moreover, CMS and Plaintiff Fund agreed on the amount of a lump sum payment to resolve Plaintiff Fund's claims existing prior to January 1, 2012, that might have been submitted pursuant to the IPP. CMS made this payment to Defendant Fund on June

18, 2012. (Def.'s Mot. at 4-5.)

Plaintiff Fund now complains that the newly operational IPP process violates 42 U.S.C. § 1395u(b)(6)(B) and 42 C.F.R. § 424.66 by requiring it to submit diagnosis codes for drug reimbursement claims.

II. Analysis

The sole issue that this Court must decide is the legal question raised in the Fund's response – whether the Indirect Payment Procedure (IPP) that the HHS recently implemented complies with the governing statute, 42 U.S.C. § 1395u(b)(6)(B), and regulation, 42 C.F.R. § 424.66.[5] More precisely, the issue is whether the governing statute and regulation allow HHS to apply Medicare Part B enrollment and claims processing requirements to Part B claims submitted by complementary insurers, like Plaintiff Fund, via the IPP process. Plaintiff Fund argues that HHS cannot do so because once a complimentary insurer like it satisfies the requirements of the governing statute, 42 U.S.C. § 1395u(b)(6)(B), that complimentary insurer is entitled to reimbursement for Medicare Part B payments, and HHS may not add any additional requirements. (Pl.'s Resp. at 9-12.) Defendant HHS argues that its interpretation of § 1395u(b)(6) is entitled to deference under *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984), because it falls "within the bounds of reasonable interpretation." *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 453 (1999). This Court agrees with Defendant HHS.

A. *Chevron* Deference Applies

As the Sixth Circuit recently observed, because the Court's "decision here involves

[5]Plaintiff Fund's additional argument that the new IPP does not comply with this Court's February 24, 2010 Order is entirely dependent upon the Court's answer to this legal issue.

interpretation of a statute administered by a federal agency," it is reviewed under the standard set out by the Supreme Court in *Chevron*. *Hadden v. United States*, 661 F.3d 298, 301 (6th Cir. 2011), *cert. denied*, No. 11-1197, 2012 WL 1106757 (U.S. Oct. 1, 2012). "Under that standard, if 'Congress has directly spoken to the precise question at issue' in the text of the statute, [the Court] give[s] effect to Congress's answer without regard to any divergent answers offered by the agency or anyone else." *Id*. (quoting *Chevron*, 467 U.S. at 842-43). "But, 'if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.'" *Id*. (quoting *Chevron*, 467 U.S. at 843). As the *Chevron* Court instructed,

> If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute.

467 U.S. at 844.

Thus, under the familiar framework of *Chevron*, this Court (1) "must decide whether the statute unambiguously forbids the Agency's interpretation, and if not, (2) whether the interpretation, for other reasons, exceeds the bounds of the permissible." *Barnhart v. Walton*, 535 U.S. 212, 218 (2002) (citing *Chevron*, 467 U.S. at 843). Moreover, "[t]he Supreme Court has made clear that courts must give heightened deference to the Secretary's interpretation of a complex and highly technical regulatory program such as Medicare." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) (internal quotation marks and citations omitted).

B. The Governing Statute is Silent on the Precise Question Presented

Section 1395u(b) addresses Medicare Part B payments, and § 1395u(b)(6) begins with the general rule that "[n]o payment under this part for a service provided to an individual shall . . . be made to anyone other than such individual or (pursuant to an assignment . . .) the physician or other person who provided the service" and then provides exceptions to that general rule. Subsection 1395u(b)(6)(B) provides one such exception, i.e., that "payment may be made to an entity" like Plaintiff Fund or other complementary insurers if that entity (1) "provides coverage of the services under a health benefit plan, but only to the extent that payment is not made under this part," (2) "has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service," and (3) is the entity "to which the individual has agreed in writing that payment may be made under this part." 42 U.S.C. § 1395u(b)(6)(B) (emphasis added).

It is not disputed that § 1395u(b)(6)(B) applies to complementary insurers like Plaintiff Fund. Rather than guaranteeing payment of submitted claims as Plaintiff Fund argues, § 1395u(b)(6)(B)'s plain language merely permits entities like Plaintiff Fund and other complementary insurers to submit claims to Medicare for reimbursement. Precisely, it expands, beyond individuals, physicians, and service providers, those who may submit a claim for reimbursement for "the amount payable under [Medicare Part B]." *Id*. The plain words of § 1395u(b)(6)(B) do not command the Secretary to pay all Medicare Part B claims submitted via the IPP process, nor does it forbid the Secretary from requiring evidence, i.e., diagnostic codes, to facilitate the determination that a submitted claim for drugs is payable under Medicare Part B.

To read § 1395u(b)(6)(B) as Plaintiff Fund proposes would render it inconsistent with

§ 1395y(a) which provides, in pertinent part, that:

> Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services –
>
> (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . .

42 U.S.C. § 1395y(a)(1)(A) (emphasis added). *See Maximum Comfort, Inc. v. Leavitt*, 512 F.3d 1081, 1087 (9th Cir. 2007) (rejecting an argument advanced by the supplier of power-operated wheelchairs to Medicare beneficiaries that the statutory subsection requiring a certificate of medical necessity, 42 U.S.C. § 1395m(j)(2), commands the Secretary to "accept the certificate of medical necessity as conclusive for purposes of reimbursing the equipment supplier" and "precludes the Secretary from requiring additional evidence, beyond the certificate, to establish medical necessity for equipment supplied" because "the plain words of § 1395m(j)(2) fail to impose any such restraint upon the Secretary" because "reading such a limitation on the Secretary's powers into that provision would be inconsistent with § 1395y(a)").

The statute at issue here, 42 U.S.C. § 1395u(b)(6)(B), sets out the requirements that must be satisfied to permit an entity like Plaintiff Fund and other complementary insurers to submit claims to Medicare for reimbursement. It is silent as to conditions for payment. 42 C.F.R. § 424.66(a) provides those conditions, including the submission of "any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program." 42 C.F.R. § 424.66(a)(5) (emphasis added).

Making rules, regulations, and establishing procedures as to how and what

complementary insurers like Plaintiff Fund must submit for reimbursement of Medicare B drug claims is exactly the types of ministerial matters that fall squarely within the HHS's authority to determine. *See* 42 U.S.C. § 405(a), incorporated into the Medicare statute by 42 U.S.C. § 1395ii (providing that the Secretary has "full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions" of the Medicare statute, "which are necessary or appropriate to carry out" those provisions). *See, e.g., Methodist Hosp. of Sacramento*, 38 F.3d at 1230 (observing that "Congress through its silence delegated" to the Secretary decisions about how the wage index component of Medicare inpatient hospital payments should be constructed and "how often she must revise it"). Thus, contrary to Plaintiff Fund's arguments here, 42 U.S.C. § 1395u(b)(6)(B) does not unambiguously forbid the Secretary's interpretation that Medicare B enrollment and claims processing requirements be applied to Part B claims submitted by complementary insurers like Plaintiff Fund via the IPP process. Despite Plaintiff Fund's arguments to the contrary, the Secretary's decision to do so is based on a permissible construction of the statute.

C. The Secretary's Statutory Construction is Reasonable and Permissible

The Secretary's decision to apply Part B claims processing requirements to complementary insurers like Plaintiff Fund using the IPP process is a reasonable interpretation of § 1395u(b)(6)(B). First, the Secretary has a fiduciary duty to ensure that Medicare claims are adjudicated correctly and that payments from the Part B Trust Fund are made only when Medicare requirements are satisfied. Second, the basis for determining the amount payable under Part B for an item or service furnished to a Medicare beneficiary is largely the same regardless of who will ultimately be paid. Thus,

consistent application of the claim adjudication model used for reimbursement of Part B claims is administratively more efficient than creating another stand-alone process for use by entities like Plaintiff Fund under the IPP scheme. Third, the statutory provision creating the IPP also creates six other scenarios where payment may be made to someone other than the beneficiary or the physician who provided the service and each of these alternative recipients is paid through the regular claims administration process. *See* 42 U.S.C. § 1395u(b)(6). Fourth, the Secretary has always required insurers submitting claims through the IPP to comply with Medicare Part B enrollment and claims processing requirements.[6] Finally, although claims submitted under the IPP must meet the same requirements of any Medicare Part B claim, the agency points to many changes that it has made to accommodate the fact that Plaintiff Fund is neither a provider nor a supplier.[7] For the

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[6]The Medicare Carriers Manual governing the prior implementation of the IPP required complementary insurers to "furnish sufficient diagnostic information and itemization of services it has paid for (with dates of services, places of services, and charges) to enable a coverage and a reasonable charge determination to be made." *Medicare Carriers Manual*, Pub. 14-3, Part 3, § 7065 at 7-45 (1988) (emphasis added). In addition, these manual instructions made clear that Medicare is not obligated to pay for every single claim that is submitted by an IPP entity. *See id.* at 7-43 - 7-44 ("The [Medicare] Program cannot: (1) guarantee payment of SMI benefits [also known as Part B benefits] on all bills of aged or disabled members; (2) undertake to inform the organization regarding which of its members are Part B enrollees; (3) check lists of members to identify those who are Part B enrollees; (4) guarantee continuation of Part B enrollment (since SMI coverage may be terminated voluntarily or for failure to pay premiums);" *see id*. at 7-42 ("The indirect payment procedure is not available when Medicare is the secondary payer or when the services are furnished by entities reimbursable on other than a reasonable charge or fee schedule basis.") (Def.'s Reply, Ex. 1, Medicare Carriers Manual, § 7065 at 7-41 through 7-48.)

[7]For example, Plaintiff Fund can self-certify that it meets the requirements in 42 C.F.R. § 424.66 through an attestation statement; Plaintiff Fund is not required to meet the durable medical equipment supplier standards (e.g., accreditation, surety bonding, licensure) found in §§ 424.57(c) and (d); it can submit a single Electronic Funds Transfer ("EFT") authorization form instead of submitting an EFT form to every contractor, and each CMS

above-stated reasons, the Secretary's interpretation of 42 U.S.C. § 1395u(b)(6)(B) is both reasonable and entitled to deference. *Your Home Visiting Nurse Servs.*, 525 U.S. at 453.

D. Plaintiff Fund's Contrary Arguments Are Not Persuasive

Plaintiff Fund argues that the Secretary cannot apply the same Medicare Part B claims processing rules that apply to providers and suppliers because Plaintiff Fund "stands in the shoes of the beneficiary." (Pl.'s Resp. at 4, 12.) As discussed above, because 42 U.S.C. § 1395u(b)(6) is silent on the issue whether IPP entities like Plaintiff Fund "stand[ ] in the shoes of the beneficiary," the Secretary's interpretation is entitled to deference. Moreover, as explained in the Federal Register, the IPP is "an alternative to Medicare payment to the beneficiary on the basis of an itemized bill or to the physician or supplier on the basis of an assignment." 53 Fed. Reg. 28384, 28385 (July 28, 1988) (emphasis added). Thus, the IPP process is not solely an alternative to paying the beneficiary as Plaintiff Fund suggests (Pl.'s Resp. at 7), it is also an alternative to paying providers and suppliers. The IPP merely allows complementary insurers, like Plaintiff Fund, to obtain an assignment of a beneficiary's right to payment from Medicare, which is the same mechanism by which providers and suppliers receive a right to be reimbursed directly from Medicare.

For the reasons discussed above, this Court rejects Plaintiff Fund's arguments that the Secretary cannot require complementary insurers to provide diagnosis codes for Part B drug claims because such a requirement is contrary to the statutory language of 42 U.S.C. § 1395u(b)(6)(B) and is thus arbitrary and capricious. (Pl.'s Resp. at 12-15.) The statute does not preclude the Secretary from imposing a diagnosis code requirement to

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contractor will accept a single enrollment application covering multiple states instead of requiring Plaintiff Fund to submit one for each state.

determine proper payment on Part B claims submitted through the IPP. Rather, the Secretary's requirement is a reasonable and permissible interpretation of 42 U.S.C. § 1395u(b)(6)(B).

E. The Secretary's Diagnosis Code Requirement is Consistent with 42 C.F.R. § 424.66(a)(5)

Moreover, contrary to Plaintiff Fund's arguments here, the Secretary's diagnosis code requirement is consistent with 42 C.F.R. § 424.66(a)(5). That subsection requires that complementary insurers, like Plaintiff Fund, must "[s]ubmit[ ] any information CMS or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program." § 424.66(a)(5) (emphasis added). The Secretary interprets this regulation as allowing her to require complementary insurers to submit diagnosis codes in order to receive reimbursement for Part B drug claims. The Secretary's interpretation of her own regulation is entitled to considerable deference and "must be given controlling weight" if it is not "plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotation marks and citation omitted). This Court rejects Plaintiff Fund's argument that § 424.66(a)(5) precludes the Secretary from going "beyond the core requirement that it obtain evidence of payment for a valid physician or supplier charge." (Pl.'s Resp. at 13.) The plain language of § 424.66(a)(5) contains no such limitation. Moreover, by providing "an itemized physician or supplier bill" after the word "including" the regulation is merely providing an example of the type of information that CMS or the carrier may request "in order to apply the requirements under the Medicare program." 42 C.F.R. § 424.66(a)(5). The plain language of § 424.66(a)(5) does not lend itself to Plaintiff Fund's argument that

this represents an exhaustive list of the type of information HHS can reasonably request as support for Medicare Part B reimbursement.

Several policy reasons also support the Secretary's diagnosis code requirement for IPP claims. As previously discussed, the Medicare program only reimburses items or services furnished to a beneficiary that are medically necessary. Requiring diagnosis codes is a reasonable means of ensuring that Medicare does not pay for an item or service that is not "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). For this reason, diagnosis codes are required on all Medicare Part B claims, including drug claims. *See Medicare Claims Processing Manual*, Pub. 100-04, Ch. 23, § 10 (requiring diagnosis codes on all claims submitted on Form CMS-1500), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf. There is no reason claims submitted via the IPP process should be exempt from this general requirement.

In addition, CMS may only pay Medicare Part B drug claims if they meet the requirements in 42 C.F.R. § 414.701. Medicare Part B provides reimbursement for a very limited category of outpatient drugs. 42 U.S.C. §§ 1395k(a)(1), 1395x(s); 42 C.F.R. § 414.701. *See also* 42 C.F.R. Part 410 (scope of Part B benefits). In general, Part B covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. *See Medicare Benefit Policy Manual*, Pub. 100-02, Chap. 15, § 50, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Examples of drugs covered by Part B include: "drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not

under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal and hepatitis vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anti-cancer drugs." 42 C.F.R. § 414.701.

As Plaintiff Fund admits, determining whether a drug is covered and payable under Medicare Part B is a difficult task, and the Secretary uses diagnostic codes to help make these determinations. For example, anti-nausea drugs are covered under Medicare Part B only when: (1) the drug is administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen; (2) the drug is initiated within two hours of the administration of the chemotherapeutic agent and continues only for a period not to exceed 48 hours from that time; and (3) the drug is used as a full therapeutic replacement for the intravenous anti-emetic drugs. *See Medicare Benefit Policy Manual*, Pub. 100-02, Chap. 15, § 50.5.4. Requiring a diagnosis code is a reasonable way for the Secretary to determine whether the anti-nausea drug was administered in connection with a chemotherapy regimen.

For these reasons, the Secretary's interpretation of 42 C.F.R. § 424.66(a)(5) as allowing her to require diagnosis codes for Part B drug claims submitted by complementary insurers like Plaintiff Fund through the IPP process, just as they are required for other Part B claims, is reasonable and entitled to deference.

F. The Secretary's Diagnosis Code Requirement is Reasonable

Plaintiff Fund argues that requiring complementary insurers like it to submit diagnosis codes on IPP drug claims is arbitrary and capricious because the Secretary does not need the diagnosis code information to process Part B drug claims. (Pl.'s Resp. at 8, 11, 13-15.) Plaintiff Fund cites the following reasons to support its argument: (1) the old IPP Form

1490U did not require diagnosis codes, (2) CMS Form 1490S does not require diagnosis codes, (3) the Retiree Drug Subsidy Program under Medicare Part D ("RDS") and the Early Retiree Reimbursement Program ("ERRP") do not require diagnosis codes, and (4) CMS was able to process Plaintiff Fund's pre-2012 drug claims without diagnosis codes. (Pl.'s Resp. at 8 n.16, 11.) The Secretary's decision to require diagnosis codes on Part B drug claims submitted through the IPP process, however, stands unless it is found to be "not rational" and not "based on consideration of the relevant factors." *FCC v. Nat'l Citizens Comm. for Broadcasting*, 436 U.S. 775, 803 (1978). Plaintiff Fund's arguments are not persuasive.

First, although the "instructions to the organizations" on CMS Form 1490U state that "[i]t is helpful if the diagnosis is also shown," claims for reimbursement submitted by complementary insurers, like Plaintiff Fund, were required to include diagnostic codes called ICD-9-CM codes. Section 4265 of the Carriers Manual titled "Billing by Organizations on CMS-1500 or CMS-1490U" states that "ICD-9-CM coding is required for each diagnosis and must correlate to each procedure or service rendered by a physician beginning April 1, 1989." *See* Dep't of HHS, CMS Transmittal 1792, Change Request 2473 to *The Medicare Carriers Manual* (2003), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1792B3.pdf.

CMS also issued a Program Memorandum on June 6, 2003 announcing its policy that a "diagnosis code must be included on all Medicare claims (electronic and paper) submitted to Part B carriers, except those claims submitted by ambulance providers." Dep't of HHS, CMS Transmittal B-03-045, Program Mem. Re: ICD-9-CM Coding Requirements for Claims Submitted to Medicare Carriers (2003), *available at* http://www.cms.gov/Regulations-and-

Guidance/Guidance/Transmittals/Downloads/B03045.pdf. This policy applied to claims submitted via CMS Form 1490U, which is a paper claim submitted to a Medicare Part B Carrier. *See* CMS Form 1490U Instructions and Dep't of HHS, CMS Transmittal 1144, Change Request 5390 to *The Medicare Claims Processing Manual* (2006), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1144CP.pdf. Accordingly, Plaintiff Fund is mistaken in its belief that diagnosis codes were not required for reimbursement of Part B claims submitted on CMS Form 1490U.

Plaintiff Fund next argues that diagnosis codes are not necessary because CMS Form 1490S does not require such codes. This argument fails to appreciate that this Form, titled "Patient's Request for Medicare Payment," is used solely by Medicare beneficiaries who complete and file their own claims, not by complementary insurers like Plaintiff Fund. *See Medicare Claims Processing Manual*, Pub. 100-4, Chap. 1, § 70.8.4, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf. In those rare instances where a beneficiary must submit his or her own claims, CMS does not penalize the beneficiary for providing a narrative description of the illness instead of annotating the claim with the diagnosis code. That the Secretary has determined it will not penalize an individual beneficiary for not providing a diagnosis code does nothing to advance Plaintiff Fund's argument that such codes are not necessary for the Secretary's determination whether a Part B drug claim is properly payable. That the Secretary accepts the cost burden of developing the claim and securing the diagnostic information needed to adjudicate that claim does not support Plaintiff Fund's argument that diagnostic information is not needed.

Plaintiff Fund's third argument addresses the claims processing information required or not required under the federal government's Retiree Drug Subsidy ("RDS") program and Early Retiree Reinsurance Program ("ERRP"). The requirements of these programs, however, do not demonstrate that the Secretary's diagnosis code requirement for Medicare Part B claims is arbitrary and capricious.

The Retiree Drug Subsidy program is an alternative to Medicare Part D drug coverage. Under that program, CMS pays an employer a 28% subsidy if the employer provides drug coverage for its retirees. 42 C.F.R. § 423.886. The RDS program does not reimburse drug claims. It provides a subsidy for Part D drugs, i.e., FDA-approved prescription drugs that are not covered by Medicare Parts A or B. *See id*. *See also* 42 C.F.R. § 423.100 (definition of Part D drug). The Secretary does not need diagnosis codes under the RDS program because HHS is not paying for Part B drugs or reviewing claims for reimbursement.

The Early Retiree Reinsurance Program was created by the Affordable Care Act to help encourage employers to continue to provide health care coverage for their employees who retire early (people 55-64 years old). 75 Fed. Reg. 24450, 24450-52 (May 5, 2010). Under this program, employers can be reimbursed for 80% of health benefit costs per person, falling between $15,000 - $90,000. *See* 42 C.F.R. §§ 149.100(a), 149.115; *see also* 42 C.F.R. § 149.1 (defining health benefits). Reimbursed health costs under ERRP include prescription drug benefits covered under and otherwise reimbursed under Medicare Part B and Part D. *See* 42 C.F.R. §§ 149.100(a), 149.2; CMS, Common ERRP Questions - Costs and Reimbursement, *available at* http://www.errp.gov/faq_costs.shtml. Because the Secretary pays 80% of all prescription drug claims submitted under the ERRP, there is no

need to distinguish between Part B and Part D drugs and thus no need for diagnosis codes. In addition, CMS does not need diagnosis codes to determine whether a drug is medically necessary under ERRP because HHS made a policy decision to defer to the medical necessity determinations made by the applicable sponsor's plan. *See Office of Consumer Information and Insurance Oversight, Claims Ineligible for Reimbursement Under the Early Retiree Reinsurance Program* (Sept. 28, 2010), *available at* http://www.errp.gov/Downloads/Claims_Eligible_for_Reimbursement[1].pdf.

Plaintiff Fund's fourth and final argument that diagnosis codes are unnecessary is disingenuous. Plaintiff Fund argues that, because the Secretary was able to process its pre-2012 Part B drug claims without the diagnosis codes, it does not need them to determine whether its post-January 1, 2012 Part B drug claims are properly payable. (Pl.'s Resp. at 8 n.16.) As pointed out by the Secretary, the process CMS developed to analyze Plaintiff Fund's pre-2012 claims included a requirement that the Fund provide diagnosis codes. Considering the age of the claims and in order to facilitate a quicker resolution of these old claims, CMS decided, during negotiations, to waive this requirement for the finite universe of Plaintiff Fund's pre-2012 claims. The Medicare contractor that reviewed Plaintiff Fund's pre-2012 claims extensively investigated each sample claim Plaintiff Fund provided to determine whether it was properly payable. This additional effort was necessitated, in part, because Plaintiff Fund did not provide diagnosis codes. The Secretary informs the Court that it is not administratively feasible for CMS to dedicate such extensive resources to evaluate all claims submitted by complementary insurers, like Plaintiff Fund, through the IPP process. Moreover, CMS has continuously advised Plaintiff Fund that diagnosis codes are required for all claims with dates of service after January 1,

2012. *See* 8/25/11 ltr. from L. Turner.

G. Secretary's Requirement for Diagnosis Codes Is Not Arbitrary and Capricious

Plaintiff Fund also argues that the Secretary's requirement that complementary insurers provide diagnosis codes on all Part B drug claims submitted through the IPP process is arbitrary and capricious because it is tantamount to a denial of those claims. (Pl.'s Resp. at 7-8.) Because this information is not in the possession of Plaintiff Fund, its Pharmacy Benefit Manager, or the dispensing pharmacy, the Fund argues, it cannot provide this admittedly relevant information. This Court rejects Plaintiff Fund's arguments.

Plaintiff Fund's conclusion that pharmacies do not collect diagnosis codes is incorrect. They do when they must furnish this information to insurers in order to get paid. For example, pharmacies enrolled in the Medicare program furnish diagnostic information for each Part B drug claim. *See, e.g., Medicare Claims Processing Manual*, Pub. 100-04, Chap. 20, Section 110.1, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf.

Plaintiff Fund is also mistaken in alleging that diagnostic codes are "not available" to it or its Pharmacy Benefit Manager.[8] If either Plaintiff Fund or its Pharmacy Benefit Manager do not get diagnostic information from dispensing pharmacies, it is because they have failed to request it – not because the information is unavailable to them or because they lack the ability to request it.

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[8]The Secretary informs the Court that, to its knowledge, no Pharmacy Benefit Manager (PBM) has enrolled as a supplier under Medicare Part B; and if a PBM did enroll as a billing agent and submitted Part B claims, it would need to include diagnosis codes on its drug claims in order to receive payment.

As the Secretary points out, Plaintiff Fund could have allowed the physician or other supplier to bill Medicare under the normal process and then reimburse the beneficiary for his or her out-of-pocket expenses under the terms of the contract between Plaintiff Fund and its insured. Instead, Plaintiff Fund chose to interpose itself between the Medicare program and the beneficiary and his physician. Having done so, Plaintiff Fund must comply with the Secretary's reasonable requirements to receive reimbursements for Part B drug claims submitted through the IPP process. Plaintiff is not entitled to any more relief than it has already obtained, and its suit is hereby dismissed.

IV. Conclusion

For the above-stated reasons, Defendant's motion to dismiss is GRANTED.

s/Nancy G. Edmunds
Nancy G. Edmunds
United States District Judge

Dated: October 30, 2012

I hereby certify that a copy of the foregoing document was served upon counsel of record on October 30, 2012, by electronic and/or ordinary mail.

s/Carol A. Hemeyer
Case Manager